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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,401	04/05/2006	Russell Edward Morris	9013-72	6024
20792 7590 12/22/2010 MYERS BIGEL, SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627				
EXAMINER				
JOHNSON, KEVIN M				
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1732				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/562,401

**Applicant(s)**

MORRIS ET AL.

**Examiner**

KEVIN M. JOHNSON

**Art Unit**

1732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 and 42-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 42-52 is/are rejected.
- 7) ☒ Claim(s) 44 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-040)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/6/2010 has been entered.

### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on 8/6/2010 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Objections***

3. Claim 44 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim is directed to a composition, but the only limitation in the instant claim that is not present in the parent claim is "said composition is sealed inside an airtight package." This limitation does not further limit the composition because being sealed in an airtight package would not alter the composition in any way. Limitations on the container in which a composition exists do not fall within the scope of a claim drawn to a composition.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-8 and 42-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims require a composition that includes a "pharmaceutical, nutraceutical or cosmetic carrier" but it is not clear from the instant disclosure what the requirements for a pharmaceutical, nutraceutical or cosmetic carrier. As a result it would not be possible for one of ordinary skill in the art at the time of the invention to determine what carriers meet the requirements of the instant claims. For the purposes of examination, the claims have been interpreted as requiring the presence of a carrier.

Instant claims 7, 8 and 42, are also indefinite because the method for forming the monolith recited in the claims requires pressing a powdered zeolite or by mixing a powdered zeolite with a binder. The claims are ambiguous with regard to the disposition of the "pharmaceutical, nutraceutical or cosmetic carrier" required by independent claim 1, and one of ordinary skill in the art would not be able to determine whether the carrier was present in the monolith or not.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-4, 6-8, 42-44 and 50-52 are and rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (Langmuir, 1993, 9, pp. 2337-2343) in view of Wu (US 5492883).

In regard to claims 1-4 and 6-8, Zhang discloses a zeolite that contains reversibly adsorbed NO (abstract). An exemplary embodiment of such a zeolite is a Na-MFI type zeolite, in which the degree of cation exchange is 100% (table I). A 100% exchanged zeolite inherently has a number of exchanged cations equivalent to, when their charge

is considered, the number of aluminum atoms contained in the framework as required by the instant claims. The zeolite material is in the form of a powder (p. 2338, IR measurement). It should be noted that according to the instant claims any of x, y or v may be zero. The material disclosed by Zhang meets the requirements of the instant claims, as both x and y may be zero. Zhang teaches that a self-supporting monolith may be formed from the powder by compressing the powder for 30 minutes (p. 2338, IR measurement), but fails to disclose that a binder is employed.

Wu discloses a method of combining a zeolite material and an organic binder, and then extruding the composition to form a monolithic structure (column 3, lines 50-62).

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize a binder as disclosed by Wu in the formation of the monolith taught by Zhang. Such a modification would have been motivated by the teaching in Zhang that the zeolite material may be formed in to a monolith, and the disclosure by Wu of a method for the formation of a zeolite containing monolith incorporating a binder. The binder disclosed by Wu would constitute a carrier as required by the instant claims.

In regard to claim 42, Wu discloses that the binders may consist of polymers, such as polyvinyl alcohols (column 5, lines 54-59). The instant claim depends from claim 8, which requires that the binder be "selected from ceramic binders, polymeric binders and other polymers." The limitations in the instant claim regarding the materials that are considered ceramic binders and polymeric binders do not place any limitations on the "other polymers" classification of the parent claim nor limit the binder selection to

only the ceramic and polymeric binder classifications. The polyvinyl alcohol binder disclosed by Wu therefore meets the requirements of the instant claim because, as the limitations on the ceramic and polymeric binder classifications in the instant claim make clear, it would be classified in the "other polymers" group.

In regard to claim 43, the material disclosed by Zhang is dried prior to NO adsorption (page 2338, column 1).

In regard to claim 44, the language in the claim directed to the composition being sealed in an airtight package is not an appropriate limitation because the claim is directed to a composition. All limitations of the instant claim are addressed in the rejection of claim 1 above.

In regard to claims 50-52, the binder disclosed by Wu is a carrier that meets the requirements of the instant claims.

10. Claims 1-4, 6, 43, 44, 46 and 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. (JP 08092051 A) in view of Zhang and Green et al. (US 5814666).

In regard to claims 1-4, 46 and 49, Yamamoto discloses a deodorizing cosmetic. The composition comprises an antimicrobial zeolite and a silicone carrier (abstract). The zeolite disclosed by Yamamoto does not meet the requirements of the instant claims.

Zhang discloses a zeolite that contains reversibly adsorbed NO (abstract). An exemplary embodiment of such a zeolite is a Na-MFI type zeolite, in which the degree of cation exchange is 100% (table I). A 100% exchanged zeolite inherently has a number of exchanged cations equivalent to, when their charge is considered, the

number of aluminum atoms contained in the framework as required by the instant claims. The zeolite material is in the form of a powder (p. 2338, IR measurement). It should be noted that according to the instant claims any of x, y or v may be zero. The material disclosed by Zhang meets the requirements of the instant claims, as both x and y may be zero.

Green discloses that compositions capable of releasing nitric oxide have an antimicrobial effect (column 4, lines 37-47).

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the zeolite disclosed by Zhang in the carrier containing deodorizing cosmetic composition disclosed by Yamamoto. Such a modification would have been motivated by the teaching in Yamamoto that the composition includes antimicrobial zeolites, and the disclosure in Green that materials capable of releasing nitric oxide exhibit antimicrobial functionality and the disclosure in Zhang of zeolites have the capability to release adsorbed nitric oxide.

In regard to claim 6, Yamamoto discloses that the cosmetic may be in the form of a powder or stick.

In regard to claim 43, the material disclosed by Zhang is dried prior to NO adsorption (page 2338, column 1).

In regard to claim 44, the language in the claim directed to the composition being sealed in an airtight package is not an appropriate limitation because the claim is directed to a composition. All limitations of the instant claim are addressed in the rejection of claim 1 above.



In regard to claims 50-52, the silicone carrier disclosed by Yamamoto is a carrier that meets the requirements of the instant claims.

11. Claims 1-4, 44, 45, 47, 48 and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry et al. (US 2000/64506 A1) in view of Zhang and Barry.

In regard to claims 1-4, 45, 47, 48 and 50-52, Barry discloses a stent that incorporates an antimicrobial agent. The antimicrobial agent is preferably a zeolite that exhibits antimicrobial activity (page 3, lines 2-3). The zeolite may be incorporated in to the stent as part of a resin powder that is prayed on to the stent (page 7). The resin powder that the zeolite is incorporated in to meets the carrier requirements of the instant claims. The zeolite employed by Barry does not meet the requirements of the instant claims.

Zhang discloses a zeolite that contains reversibly adsorbed NO (abstract). An exemplary embodiment of such a zeolite is a Na-MFI type zeolite, in which the degree of cation exchange is 100% (table I). A 100% exchanged zeolite inherently has a number of exchanged cations equivalent to, when their charge is considered, the number of aluminum atoms contained in the framework as required by the instant claims. The zeolite material is in the form of a powder (p. 2338, IR measurement). It should be noted that according to the instant claims any of x, y or v may be zero. The material disclosed by Zhang meets the requirements of the instant claims, as both x and y may be zero.

Green discloses that compositions capable of releasing nitric oxide have an antimicrobial effect (column 4, lines 37-47).

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the zeolite material disclosed by Zhang in the stent described by Barry. Such a modification would have been motivated by the teaching in Green that materials capable of releasing nitric oxide exhibit antimicrobial functionality, Zhang's disclosure of zeolites have the capability to release adsorbed nitric oxide and the teaching in Barry that zeolites with antimicrobial functionality may be beneficially included in stents.

12. Claims 1, 5, 6, 44, 46 and 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto in view of Rudolf et al. (Journal of Magnetic Resonance, 2002, 155, pp. 45-56) and Green.

In regard to claims 1, 5, 46 and 49, Yamamoto discloses a deodorizing cosmetic. The composition comprises an antimicrobial zeolite and a silicone carrier (abstract). The zeolite disclosed by Yamamoto does not meet the requirements of the instant claims.

Rudolf discloses a sodium exchanged type-A zeolite, Na-A, for use in the adsorption and desorption of NO. Zeolite-A has the LTA structure required by the instant claims.

Green discloses that compositions capable of releasing nitric oxide have an antimicrobial effect (column 4, lines 37-47).

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the zeolite disclosed by Rudolf in the carrier containing deodorizing cosmetic composition disclosed by Yamamoto. Such a modification would have been motivated by the teaching in Yamamoto that the composition includes antimicrobial

zeolites, and the disclosure in Green that materials capable of releasing nitric oxide exhibit antimicrobial functionality and the disclosure in Rudolf of zeolites have the capability to release adsorbed nitric oxide.

In regard to claim 6, Yamamoto discloses that the cosmetic may be in the form of a powder or stick.

In regard to claim 44, the language in the claim directed to the composition being sealed in an airtight package is not an appropriate limitation because the claim is directed to a composition. All limitations of the instant claim are addressed in the rejection of claim 1 above.

In regard to claims 50-52, the silicone carrier disclosed by Yamamoto is a carrier that meets the requirements of the instant claims.

13. Claims 1, 5, 44, 45, 47, 48 and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry et al. (US 2000/64506 A1) in view of Zhang and Barry.

In regard to claims 1-4, 45, 47, 48 and 50-52, Barry discloses a stent that incorporates an antimicrobial agent. The antimicrobial agent is preferably a zeolite that exhibits antimicrobial activity (page 3, lines 2-3). The zeolite may be incorporated in to the stent as part of a resin powder that is prayed on to the stent (page 7). The resin powder that the zeolite is incorporated in to meets the carrier requirements of the instant claims. The zeolite employed by Barry does not meet the requirements of the instant claims.

Rudolf discloses a sodium exchanged type-A zeolite, Na-A, for use in the adsorption and desorption of NO. Zeolite-A has the LTA structure required by the instant claims.

Green discloses that compositions capable of releasing nitric oxide have an antimicrobial effect (column 4, lines 37-47).

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the zeolite material disclosed by Rudolf in the stent described by Barry. Such a modification would have been motivated by the teaching in Green that materials capable of releasing nitric oxide exhibit antimicrobial functionality, Rudolf's disclosure of zeolites have the capability to release adsorbed nitric oxide and the teaching in Barry that zeolites with antimicrobial functionality may be beneficially included in stents.

### ***Response to Arguments***

14. Applicant's arguments with respect to claims 1-8 and 42-52 have been considered but are moot in view of the new ground(s) of rejection.

The argument that the zeolites disclosed by Zhang are not suitable for desorption of NO at temperatures useful for the purposes required by the instant claims is not persuasive. Zhang teaches that the reversible and irreversible NO adsorption capacity of the zeolites is measured at 273K (page 2338, column 2) which is below the temperature at which the composition of the instant claims must be useful, and as pointed out by applicant the zeolites exhibit desorption peaks at temperatures in excess of those useful for the purposes required by the instant claims. Therefore, one of ordinary

skill in the art at the time of the invention would expect that the temperature range between these extremes, the ambient and physiological conditions at issue in the instant claims, would also demonstrate the potential for reversible adsorption of NO on the zeolites disclosed by Zhang.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN M. JOHNSON whose telephone number is (571)270-3584. The examiner can normally be reached on Monday-Friday 9:00 AM to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Curtis Mayes can be reached on 571-272-1234. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin M Johnson/

/David M Brunsman/

Art Unit: 1732

Examiner, Art Unit 1732

Primary Examiner, Art Unit 1732